Sample Tasks for Notional Products

Two sample tasks are described below, followed by a list of specific items that the offeror should submit as part of their proposal. **The purpose of the Sample Tasks is to evaluate the offeror's understanding of MCM manufacturing and regulatory processes for FDA approval and the offeror's ability to plan and schedule manufacturing of MCMs in the proposed MCM ADM facility.** These are notional tasks for evaluation purposes and do not indicate any intention on the part of the Government to provide a contract to the Offeror to develop the products. In providing the requested items for each task, the Offeror should assume that the tasks are wholly independent and not concurrent.

1) Large Molecule Task. This task includes three elements, as follows:

   a) Development of a vaccine effective against a gram negative bacterium, using recombinant technology based on a microbial expression system. "Development" for this task is to include assembly and submission of the IND (ADM will be holder of the IND) through FDA approval/licensure; please exclude post-marketing surveillance in your plan.
      (1) Assume that all IND enabling studies have been completed, including the manufacture and release of Phase I clinical material.
      (2) Assume that the IP holder of the molecule performs no role in the development program. The ADM is to act as the Sponsor.

   b) Post-approval production of 4,000,000 doses in the first year and 1,500,000 doses per year thereafter.
      (1) Assume that "production" includes fill/finish.
      (2) Technical Assumptions (These minimal assumptions are provided to allow maximum innovation on the part of the Offeror to approaching the task.)

         (a) Product Drug Substance Yield: 2 g/l

         (b) Dose: 100 µg / Route of Administration is IM / 1 Dose per Vial

         (c) Number of doses for protection: 3

         (d) Purity: 95%

         (e) Expression System: Microbial

   c) Post-approval surge production of 4,000,000 doses in three (3) months from the moment of the DoD's request to initiate surge production.
      (1) Assume that the product has already been approved and that production as described in item (b) above has been ongoing.
      (2) Assume that surge production includes fill/finish.

2) Small Molecule Task - This task includes three elements, as follows:

   a) Development of a bifunctional acetylcholinesterase reactivator for treatment of nerve agent exposure. "Development" for this task is to include assembly and submission of

the IND (ADM will be holder of the IND) through FDA approval/licensure; please exclude post-marketing surveillance in your plan.

(1) Assume that all IND enabling studies have been completed, including the manufacture and release of Phase I clinical material.
(2) Assume that the IP holder of the molecule performs no role in the development program. The ADM is to act as the Sponsor.

b) Post-approval production to provide 1,500,000 doses per year.

(1) Assume that "production" yields finished product ready for distribution.
(2) Technical Assumptions (These minimal assumptions are provided to allow maximum innovation on the part of the Offeror to approaching the task.)

(a) Yield: 50%

(b) Dose: 200 mg/dose / Route of Administration is IM / 1 Dose per Vial

(c) Doses per course: 3

c) Post-approval surge production of 12,000,000 doses in three (3) months from the moment of the DoD's request to initiate surge production

(1) Assume that the product has already been approved and that production as described in item (b) above has been ongoing.
(2) Assume that surge production yields finished product ready for distribution.

In describing how each task will be performed, the Offeror must provide the following items (separately for each sample task) as part of their proposal:

a) An Integrated Master Plan that clearly indicates the critical path and major milestones to product approval, the first year of post-approval manufacturing, and surge production. The IMP, Technical Approach Summary (TAS) / Product Development Plan (PDP) and Risk Management Plan must be included descriptions of each of the following, at a level of detail sufficient to allow for evaluation of the Offeror's ability to develop the proposed vaccine using the ADM capability it proposes.

i) Tasks/functions to be performed, along with cycle times, risk, risk management and opportunities:
   (1) The Offeror is to develop a Work Breakdown Structure (WBS) to level four (4) for the tasks to be performed, along with associated cost, time and risk/opportunity estimates and a description of the major assumptions that drove the cost and time estimates. A template has been provided for completion that should be used by the Offeror (see accompanying Excel workbook). Please see the completion instructions associated with the template. The provided grid may be supplemented with a narrative document if needed to fully describe the development and production strategy.
   (2) If the Offeror's plan for performing the sample task does not fit the WBS template provided, the Offeror is to complete the template, but may offer a separate description of the preferred, alternative approach along with a description of why this approach is preferred.

ii) Support and Management

(1) Personnel:
    (a) Numbers and types (i.e. education/skill level) of people, by functional area, to be used on the project (include management and technical staff)
    (b) Costs associated with the staffing identified for the project

(2) Other entities:
    (a) Describe, by functional area, any entities other than the ADM (i.e. subcontractors) that will be used to complete the sample task
    (b) Time and cost commitments for each entity involved

Description of lines of authority within the ADM and between the ADM and other entities, sufficient to ensure successful completion of the project

iii) Plan, including timing (reflected in schedule), for quickly converting suites to surge production of the product once it is approved

iv) Facilities & Equipment:
(1) Types of facilities and equipment used that will enable manufacturing innovation and how innovative technologies supporting flexible manufacturing can be incorporated to upgrade the facilities.

v) Critical Milestones
(1) The IMP shall outline key, critical path milestones, with *"GO/* NO GO" decision criteria (entrance and exit criteria for each phase of the project). This should include, but not be limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions to support product approval/licensure under the animal rule.

b) Integrated Master Schedule - The Offeror(s) shall deliver a program-level Integrated Master Schedule (IMS) (e.g., Gantt Chart in MS Project) that correlates with the IMP and WBS. Schedules should account for the time needed by the USG for review of critical documentation. Such reviews would include, but are not limited to, critical milestone decision reviews by DoD, and FDA reviews of protocols, study results, etc.
i) The IMS must be “nested” and be able to roll up all time-phased elements.
ii) The IMS critical path must be highlighted.
iii) The IMS shall include the dependencies that exist between tasks.
iv) The IMS should be based on the expected (50% probability) cycle times as described in the WBS.